



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0627]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on March 29 and 30, 2018, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg; Salons A, B, C, and D; 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993, patricio.garcia@fda.hhs.gov; 301-796-6875, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A

notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On March 29, 2018, the committee will discuss, make recommendations, and vote on information regarding a premarket approval application to market a novel continuous glucose monitoring (CGM) device system, the Senseonics, Inc. Eversense CGM System. This device requires minor surgery to implant and remove, and if approved, would provide 90 days of sensor glucose values from each implanted sensor.

The Eversense CGM System measures patients' glucose concentrations from subcutaneous interstitial fluid similar to approved CGM systems. All CGM devices currently or previously marketed used electrochemistry to measure glucose in interstitial fluids, last for 3 to 11 days and are inserted via a small-gauge needle by the end user. The proposed CGM system uses a fluorescence-based measurement technique, requires minor surgery for subcutaneous implantation, and will have a 90-day sensor wear period. The proposed CGM sensor also includes a drug component (dexamethasone acetate) intended to mitigate negative effects on sensor accuracy and sensor life from the foreign body response at the sensor insertion site. The proposed intended use, as stated by the sponsor, is as follows:

The Eversense CGM System continually measures glucose levels in adults (age 18 and older) with diabetes for the operating life of the sensor.

The system is intended to:

- Aid in the management of diabetes.
- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns seen over time.

On March 30, 2018, the committee will discuss and make recommendations regarding measuring blood glucose using capillary blood with blood glucose meters in all hospital patients, including those receiving intensive medical intervention/therapy and patients with decreased peripheral blood flow, such as with severe hypotension, shock, hyperosmolar-hyperglycemia and severe dehydration (e.g., patients in intensive care settings). Currently, FDA has cleared one glucose meter for use all over the hospital using venous and arterial blood. FDA understands that being able to make capillary blood measurements in all hospitalized patients using FDA cleared and Clinical Laboratory Improvement Amendments (CLIA) waived (i.e., designated as waived per the standards in the CLIA) glucose meters would be more convenient and timely for hospital staff. FDA would like to present new data from capillary blood measurements on glucose meters in patients receiving intensive medical intervention/therapy to the Clinical Chemistry and Clinical Toxicology Devices Panel. FDA would like to receive feedback from the advisory panel on the benefits and risks of measuring capillary blood using blood glucose meters in this intended use population, and the considerations for CLIA waiver for this use.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 22, 2018. Oral presentations from the public will be scheduled on March 29 and 30, 2018, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 14, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 15, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due

to a disability, please contact AnnMarie Williams, at annmarie.williams@fda.hhs.gov, 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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